K022922

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510(k) Summary

Submitted By:	LifeScan, Inc. 1000 Gibraltar Drive Milpitas, CA 95035 (408) 942-5903 (408) 942-5606 (fax)
Contact:	John E. Hughes
Date of Preparation:	September 3, 2002
Establishment Registration No:	2939301
Device Name:	Harmony™ INR Monitoring System
Common/Classification Name:	Prothrombin Time Test
Device Classification:	Class II
Regulation Number:	CFR 864.7750
Classification Panel:	Hematology
Product Code:	GJS
Predicate Device:	Rubicon™ Prothrombin Time Monitoring System K001699

Device Description:

The Harmony System consists of a meter and test strip. When a drop of blood is placed on the test strip, the blood is drawn into the reaction cells and mixed with reagents that cause blood clotting to begin. The meter monitors the blood clotting process by passing a light beam through the blood sample being tested. The meter detects blood clot formation and, at the conclusion of the test, the prothrombin time is displayed in International Normalized Ratio (INR) units.

Intended Use:

For the quantitative determination of prothrombin time (PT) in capillary whole blood by properly selected and trained patients or their caregivers, or in capillary or venous whole blood by health care professionals, as an aid in monitoring oral anti-coagulation therapy.

Comparison to Predicate Device:

The Harmony INR Monitoring System and the Rubicon Prothrombin Time Monitoring System both consist of a meter and disposable test strip. Both systems employ whole blood as a test sample and can be used by laypersons in the home environment to monitor oral anti-coagulation therapy. Both employ thromboplastin to cause blood coagulation.

The systems differ in that the Harmony System has been enhanced by reducing the number of calibration codes required which makes the product simpler to use. In addition, an active use confirmation was added to ensure the integrity of the LCD display prior to each use.

Environmental and Non-Clinical Testing:

Applicable environmental and non-clinical testing was performed per IEC 60601 and other applicable standards and procedures. The Harmony INR Monitoring System passed all tests.

Performance Testing:

The study conducted to compare equivalency of the Rubicon 510(k) cleared device to the modified Harmony System met the performance requirements for accuracy and precision relative to the reference laboratory system. Equivalent performance in meeting user requirements was determined.

Conclusion:

The test results demonstrate the Harmony INR Monitoring System is substantially equivalent to the Rubicon Prothrombin Time Monitoring System.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
2098 Gaither Road
Rockville MD 20850

SEP 3 0 2002

Mr. John E. Hughes
Senior Manager, Regulatory Submissions
LifeScan, Inc.
1000 Gibraltar Drive
Milpitas, California 95035

Re: k022922
Trade/Device Name: Harmony™ INR Monitoring System
Regulation Number: 21 CFR § 864.7750
Regulation Name: Prothrombin Time Test
Regulatory Class: II
Product Code: GJS
Dated: September 3, 2002
Received: September 4, 2002

Dear Mr. Hughes:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4588. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Steven Gutman

Steven I. Gutman, M.D., M.B.A.
Director
Division of Clinical
Laboratory Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number: K022922

Name: Harmony™ INR Monitoring System

Indications for Use:

The Harmony INR Monitoring System is indicated for the quantitative determination of prothrombin time (PT) in capillary whole blood by properly selected and trained patients or their caregivers, or in capillary or venous whole blood by health care professionals, as an aid in monitoring oral anti-coagulation therapy.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Clinical Laboratory Devices
510(k) Number K022922